Section II

FEB 2 8 2002

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K013952

Date	November 28, 2001
Submitter	Intuitive Surgical 1340 West Middlefield Road Mountain View, CA 94043
ER Number	2955842
Contact	Michael Yramategui Director, Quality and Regulatory Affairs Telephone: 650-237-7048 Fax: 650-526-2060 e-mail: mike_yramategui@intusurg.com
New Device	Name: Intuitive Surgical® Stereo View Endoscopic System Classification Name: Endoscope and Accessories — 21 CFR §876.1500 Rigid Endoscope — 21 CFR §876.1500 Gynecologic Laparoscope/Accessories — 21 CFR §884.1720 Common Name: 3-D Endoscope and Accessories
Predicate Devices	Intuitive Surgical® Stereo View Endoscopic System (legally marketed under K990188 and K001666)

Device Description	The Intuitive Surgical® Stereo View System consists of an endoscope, camera, and light source. The endoscope is essentially identical in size and shape to the predicate devices referenced above, but built by a different manufacturer. This endoscope has 3 channels allowing the surgeon to alternate between a stereo three-dimensional view and a wide angle two-dimensional view using a simple video switch that can be used to toggle between the two images. This switch is located between the camera and the Intuitive Surgical® Endoscopic Instrument Control System, on a vision system cart that includes the illumination sources, camera controllers and other video processing equipment. The camera controllers and illumination sources that attach to the endoscope and camera are identical in function to those described for the predicate devices. The intended use for the subject device is identical to the previously cleared intended use for the Intuitive Surgical® Stereo View Endoscopic System through the premarket notification process (K990188 and K001666).
Intended Use	The Intuitive Surgical® Stereo View Endoscopic System is intended for endoscopic viewing of internal surgery sites during minimally invasive surgery in the peritoneal cavity, thoracic cavity, and peritoneum. It is designed for use with the Intuitive Surgical® Endoscopic Instrument Control system during laparoscopic and thoracoscopic surgical procedures.
Comparison to Predicate Device	The basic design and function of the Intuitive Surgical® Stereo View Endoscopic System is essentially identical in terms of shape, size, materials, and function to the predicate device, except that it is built by a different manufacturer and includes an additional optical and video channel. The illuminator (light source) and light guide are similar in function to those described in the predicate system.
Technological Characteristics	The technological characteristics of the subject devices are similar to those of the predicate devices.

Performance Data	Design analysis and comparison confirm that basic functional characteristics are substantially equivalent to the predicate device cited. Components of the Intuitive Surgical® Stereo View Endoscopic System are manufactured using materials that are identical to materials used in the predicate device that have a long history of human contact bio-compatibility. Where applicable, electrical components of the Intuitive Surgical® Stereo View Endoscopic System have been tested to ensure compliance with safety characteristics described in standards from UL 2601-1, CSA C22.2 No 601.1, IEC 60601-1, IEC 60601-1-2, IEC 60601-2-18, and EN 55011, as well as relevant provisions of the European Medical Device Directive 93/42/EEC. The biocompatibility of materials used in the subject device is consistent with standards described in ISO 10993.
Conclusion	Based upon the product technical information provided, intended use, and performance information provided in this pre-market notification, the Intuitive Surgical® Stereo View Endoscopic System described herein is substantially equivalent to the current legally marketed predicate devices (K990188 and K001666).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 8 2002

Mr. Michael Yramategui
Director, Quality and Regulatory Affairs
Intuitive Surgical
1340 West Middlefield Road
Mountain View, California 94043

Re: K013952
Trade/Device Name: Intuitive Surgical® Stereo View Endoscopic System
Regulation Number: 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: November 28, 2001
Received: November 30, 2001

Dear Mr. Yramategui :

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section III

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K013952

Device name: Intuitive Surgical® Stereo View Endoscopic System

Indications for Use:

The Intuitive Surgical® Stereo View Endoscopic System is intended for endoscopic viewing of internal surgery sites during minimally invasive surgery in the peritoneal cavity, thoracic cavity, and peritoneum. It is designed for use with the Intuitive Surgical® Endoscopic Instrument Control system during laparoscopic and thoracoscopic surgical procedures.

PLEASE DO NOT WRITE BELOW THIS LINE
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X Over-the Counter Use_____

(per 21 CFR §801.109) (Optional Format 1-2-96)

for Mark N Milhouse

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013952